outside the abdomen, or nothing at all. Participants most commonly circled at least one portion of the middle (89.8%) and/or lower (92.2%) abdomen. 205 participants (49.9%) circled the median and lower abdomen only. 73 participants (17.8%) circled an area inclusive of at least a portion of all nine regions of the abdomen; of these participants, 28 (38.4%) had a self-reported history of disease(s) with abdominal symptoms (e.g., irritable bowel syndrome, GERD). **CONCLUSIONS:** Despite relatively low education levels and low prevalence of diseases with abdominal symptoms, nearly all participants demonstrated knowledge of the general location of the abdomen. However, the data suggest that nearly half of participants were considering the middle and lower regions of the abdomen exclusively. Therefore, to obtain accurate reports of symptoms pertaining to a specific abdominal location, it would behoove instrument developers to define and identify (e.g., through an illustration), the precise anatomical area of interest, which should improve the reliability and validity of the PRO measure.

PIH60

USABILITY TESTING OF AN INTEGRATED GLUCOMETER AND HANDHELD ELECTRONIC PATIENT-REPORTED OUTCOME SYSTEM

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OBJECTIVES: Clinical trials for diabetes treatment are increasingly collecting electronic patient-reported outcomes (ePRO) and physiological measurements outside of the clinical setting. This study examined the usability of a handheld ePRO device and glucometer as an integrated system for collecting, transmitting, and characterizing blood glucose readings. **METHODS:** Twelve subjects with type 2 diabetes were interviewed in the U.S. Subjects were given a handheld ePRO device (LogPad LW), synthetic glucose solution, and a Bluetooth-enabled MyGlucoHealth meter with test strips. Subjects were asked to take a glucose reading, transmit the reading to the handheld device, and characterize the glucose value in a diary. Interviewers observed subjects and conducted semi-structured interviews to determine usability of the devices and integration step. **RESULTS:** Subjects were 47 to 67 years old and 55% female. No major difficulties were observed by the interviewers. 100% of subjects found the exercise to be easy, and easily understood how to take a glucose reading, transmit it to a handheld device and to characterize the glucose reading. 75% of subjects reported that they would not be bothered by the size of the devices. All subjects (100%) reported they were willing and able to carry both devices with them and complete a diary outside of the home, and 88% of subjects would be willing to use both devices in public. When asked about additional features on the integrated system, 57% stated it would be helpful to review their most recent blood glucose readings on the handheld device, and 71% would like the ability to turn a reminder alarm on or off. **CONCLUSIONS:** An integrated handheld ePRO/glucometer system was found to be easy to use and acceptable to subjects with type 2 diabetes, and is a feasible solution for collecting, transmitting and characterizing blood glucose readings outside of the clinical setting.

PIH61

COMPARISON OF PATIENT-REPORTED OUTCOMES REQUIREMENTS IN MEDICAL GUIDELINES FOR PAIN, MIGRAINE, RHEUMATOID ARTHRITIS, AND SYSTEMIC LUPUS ERYTHEMATOSUS: EUROPE VS. UNITED STATES

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OBJECTIVES: To enable researchers to better understand the regulatory requirements for inclusion of patient-reported outcome (PRO) measures as efficacy endpoints for the development and approval of drugs for generic pain and analgesic indications, plus three pain-related diseases (i.e., migraines, rheumatoid arthritis [RA], and systemic lupus erythematosus [SLE]). This research reviews, contrasts, and compares the European Medicines Agency (EMA) and US Food and Drug Administration (FDA) medical guidelines in these conditions. **METHODS:** A targeted search was conducted for recent (2010-2015) European and US medical guidelines in the conditions mentioned. Information pertaining to PROs within these guidelines was extracted and compared. Attention was paid to similarities, differences, and gaps across these guidelines. **RESULTS:** Both EMA and FDA consistently recommend the use or development of reliable and valid measures across all disease areas and emphasized the importance of measuring symptoms from the patient perspective. For example, both authorities recommend the assessment of intensity for pain and analgesic indications; assessment of migraine-associated symptoms (nausea, vomiting, photophobia, phonophobia) for migraine treatment efficacy; and measurement of fatigue and other relevant symptoms for patients with SLE. For RA, the EMA recommends assessment of pain intensity through the use of a PRO measure. More often, EMA guidelines emphasize the requirement of assessing health-related quality of life (HRQoL) or functioning through PRO measures. This is not to say that HRQoL is not addressed by FDA guidelines (e.g., measurement of physical and emotional function and HRQoL in pain, assessment of physical function in RA); however, examples of specific assessments are more prominent within EMA guidelines. In contrast, FDA guidelines are more specific regarding how best to evaluate disease symptoms. **CONCLUSIONS:** While similarities between EMA and FDA medical guidelines exist, variations between guidelines highlight the need for sponsors to become familiar with and incorporate these guidelines early on in the drug development process.

PIH62

CAPTURING EMOTIONAL CONCEPTS DURING CONCEPT ELICITATION

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OBJECTIVES: FDA guidance for PROs has led to an increased reliance on qualitative methodologies to identify relevant domains for instrument development. Concept elicitation (CE), which underpins the development of PRO instruments, often relies on exploring patient experience through the lens of the patient as it relates to disease burden and the impact on activities of daily living. Yet the deeper emotional experience of patients is missed. We address this gap in methodology by reviewing how the use of a structured model for emotions can improve PRO instrument development by strengthening the role of emotions during CE. **METHODS:** A literature review of CE with emotional motivations was undertaken to identify the most salient aspects for PRO instrument development. **RESULTS:** The method for eliciting emotional motivations is based on motivation research and extraction techniques (see Forbes, 2010) containing, nine distinct categories of emotional motivation. The CE protocol relies upon neuroscience research (see Damasio 2010) which points to the power of a sub-800 millisecond response frame for eliciting purely emotional reactions to stimuli. Images validated in large sample research as uniquely evoking one of the nine motivational emotions are the stimuli for this emotional evocation procedure. This augmentation to typical CE has been used repeatedly to identify needs for emotional health among sufferers of diabetes, arthritis, and heart disease – in each case linking evocations to absence of needed emotional energies that could promote self-care and disease recovery. **CONCLUSIONS:** CE techniques for most PRO development do not allow investigators to sufficiently understand the patient experiences of physical symptoms, effect of ADLs, and the emotional consequences of a disease or condition of interest. Adding emotional motivation techniques to CEs will broaden our ability to capture the emotional experiences of patients so that related PRO instrument items may better represent the experiences of patients' suffering from various medical conditions.

PIH63

INADEQUATE TREATMENT OF POST-SURGICAL PAIN MAY RESULT IN EXTENDED HOSPITALIZATION PERIOD

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OBJECTIVES: Demonstrate through a retrospective analysis of secondary data, that patients with inadequate treatment of post-surgical appendectomy and colic renal pain may end up having a longer period of hospitalization. **METHODS:** A retrospective administrative claims database containing over 18 millions lives from Brazilian private hospitals (ORIZON database), was assessed (from January through June 2014), of patients who underwent a surgical intervention by appendectomy (n= 1,618) or who had an episode of renal colic and nefretic syndrome (n=6,555) identified by International Codes Disease (N20, N21, N22, N23) and who received one of the nonsteroidal anti-inflammatory drugs (NSAIDs) available in the market (parecoxib, tenoxicam, and ketoprofen, ketorolac) for pain treatment. After patient identification, the average period of hospital permanence was assessed by drug group. . Median time differences between groups were assessed thru Kruskal-Wallis method. A significance level of 5% was adopted. All statistical analysis were performe in R, version 3.1.1. **RESULTS:** The average period of hospital permanence for the appendectomy procedure was 2.20 days (medical calculations from private hospitals round it to 3 days) group of (tenoxicam, ketoprofen, ketorolac) versus 1.95 ($p=0.006$) in the parecoxib, respectively. In the episodes of renal colic, we had 33 hours versus 25 hours ($p < 0.001$) in the group of (tenoxicam, ketoprofen, ketorolac) versus (parecoxib), respectively. **CONCLUSIONS:** Pain is the one of the critical signs in clinical evolution, quality care and outcome disease. The period of hospital permanence after surgery or during renal colic or nefretic syndrome treatment is the utmost importance and implies in hospital costs. The longer patients stay in hospital higher is the probability of clinical complication, delaying treatment and some cases to increase mortality. The adequate treatment may reduce hospital stay and improve assistance as well as financial results

PIH64

SATISFACTION WITH LIFE OF GENERAL POPULATION OF PAKISTAN. A NATION WIDE SURVEY

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OBJECTIVES: To evaluate the Satisfaction with life among general population of Pakistan. **METHODS:** A cross sectional, descriptive study was undertaken with study population responding to internet survey, living all over Pakistan. Satisfaction with life was assessed using Ed diener SWLS scale. Descriptive analysis was used to elaborate people's demographic characteristics while inferential statistics were applied to report the association among study variables. **RESULTS:** Out of 2203 questionnaires filled 1507 were from Pakistan. Gender distribution was 761 (50.5%) males. Most popular age group of study participants was 20-25 years (46.6%) with 340 (22.6%) married and 669 (44.4%) having graduate level education. Overall 460 (30.5%) participants were satisfied with their lives and 190 (12.6%) were extremely satisfied from their lives. One hundred and sixty seven (11.1%) and 38 (2.5%) participants were dissatisfied and extremely dissatisfied from their lives respectively. Age and marital status had no association with satisfaction of life. Profession is one factor in dissatisfaction towards life. People in urban locality have positive trend of satisfaction when compared with the rural ones. **CONCLUSIONS:** This study provides baseline assessment for the Satisfaction with life of general population of Pakistan and the results could be applied in clinical practice. The study revealed the impact of the following conditions on the various satisfaction with life domains measured: Education, work, personal income & Locality. Overall the percentage of Pakistani people who are satisfied with their life (67.6%) is more as compared to the percentage of dissatisfied people. Satisfaction with life of general populationof pakistan could be further improved if better job and education opportunitiesare provided.

PIH65

DIFFERENTIALS IN CONTRACEPTIVE USE AMONG CURRENTLY MARRIED WOMEN BY SOCIO-DEMOGRAPHIC CHARACTERISTICS IN WESTERN KENYA

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